

# The impact of a positive psychology intervention on quality of life for women with polycystic ovary syndrome (PCOS)

<b>Submission date</b> 03/10/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder amongst women of reproductive age, affecting about 6.5% of women. PCOS is also the most prevalent cause of infertility. Women with PCOS are at an increased risk of miscarriage, cardiovascular disease, type 2 diabetes mellitus and cancer. Symptoms can include hirsutism (excessive hair growth), insulin resistance, infertility and obesity. Studies have shown that PCOS sufferers have higher levels of psychological distress than healthy individuals, including anxiety and depression. Studies show that PCOS can lead to lower quality of life and that women with PCOS are at an increased risk of suffering from a psychiatric disorder, including depression. Positive psychology interventions have been shown to help improve depressive symptoms in participants. Research has found that the positive psychology activity Three Good Things (whereby participants were asked to write down three things that went well each day and their causes) increased happiness and decreased depressive symptoms for six months. This study aims to assess the effectiveness of an online positive psychology intervention on improving the quality of life of women with PCOS.

### Who can participate?

Patients aged 18 or over who have been diagnosed with PCOS by a clinician, live in the UK and have access to the internet.

### What does the study involve?

Participants are randomly allocated to the intervention or the control group. The participants in the intervention group are invited to take part in a 4 week online positive psychology intervention. The positive psychology exercise is "Three Good Things". For this exercise participants are asked to write down three good things which have happened to them on each day of the intervention. They are directed to a website which enables them to fill in their three good things each day. Participants in the control group are asked to go about their usual routine and are offered the intervention after the follow-up period (6 weeks).

### What are the possible benefits and risks of participating?

The positive psychology intervention, "Three Good Things", has been shown to increase

happiness and decrease depressive symptoms. There are no known risks to participating in this study.

Where is the study run from?

The lead study centre is the University of Derby. The trial is being run in association with a PCOS clinic at the Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?

January 2014 to November 2015

Who is funding the study?

University of Derby (UK)

Who is the main contact?

Sophie Williams

s.williams3@derby.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Miss Sophie Williams

**Contact details**

University of Derby

Kedleston Road

Derby

United Kingdom

DE22 1GB

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s.williams3@derby.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

A randomised controlled trial to investigate whether an online psychology intervention can improve the quality of life of women with polycystic ovary syndrome (PCOS)

**Study objectives**

Women with Polycystic Ovary Syndrome (PCOS) can experience a low quality of life: a non-invasive clinical trial offering an online positive psychology intervention to women with PCOS may, therefore, be beneficial. We propose to carry out a fully randomised clinical trial into the benefits of an online positive psychology intervention for Derby-based women with PCOS over a four week period, using quality of life as an endpoint. This will be the first study to investigate whether an online intervention can improve the quality of life of women with PCOS.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. University of Derby Psychology Research Ethics Committee (PREC), 21/08/2013, ref: 087-13-SW
2. NRES Committee East Midlands Nottingham 2, 14/11/2013, REC ref: 13/EM/0393

**Study design**

Single-centre randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Polycystic Ovary Syndrome (PCOS)

**Interventions**

Randomisation shall be stratified in order to ensure an equal distribution in length of diagnosis of PCOS. Pragmatic randomisation may be used if a participant has a strong preference to be in a particular group (either control or intervention).

All participants in the control group will be offered the intervention after the follow-up period. Intervention group: Four week online positive psychology intervention - "Three Good Things" activity.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Quality of life, measured using the PCOS QoL (in development) at baseline, 4 and 6 weeks

**Secondary outcome measures**

Anxiety and depression, measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 4 and 6 weeks

**Overall study start date**

01/01/2014

**Completion date**

01/11/2015

**Eligibility****Key inclusion criteria**

1. Aged 18 or over
2. Diagnosed with Polycystic Ovary Syndrome by a clinician
3. Lives in the UK
4. Has access to the internet

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

200

**Key exclusion criteria**

1. Participants with mental incapacity unable to give informed consent
2. Participants unable to understand verbal and written information in English (as the study is an online study and so translation for individuals not able to understand English is not possible)

**Date of first enrolment**

12/01/2015

**Date of final enrolment**

17/04/2015

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

University of Derby

Derby

United Kingdom

DE22 1GB

# Sponsor information

## Organisation

University of Derby (UK)

## Sponsor details

c/o Chris Bussell

Head of Science

Kedleston Road

Derby

England

United Kingdom

DE22 1GB

## Sponsor type

University/education

## ROR

<https://ror.org/02yhrrk59>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Derby

## Alternative Name(s)

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication of a 'lessons learned paper' in a journal within the next year.

2016 results published in thesis <https://derby.openrepository.com/handle/10545/620535>

**Intention to publish date**

31/12/2018

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No